Carum – User Instructions

ARDO

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EXPLANATION

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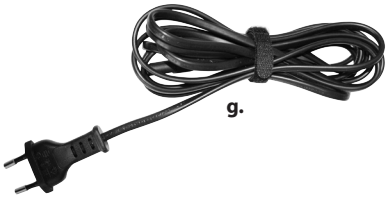
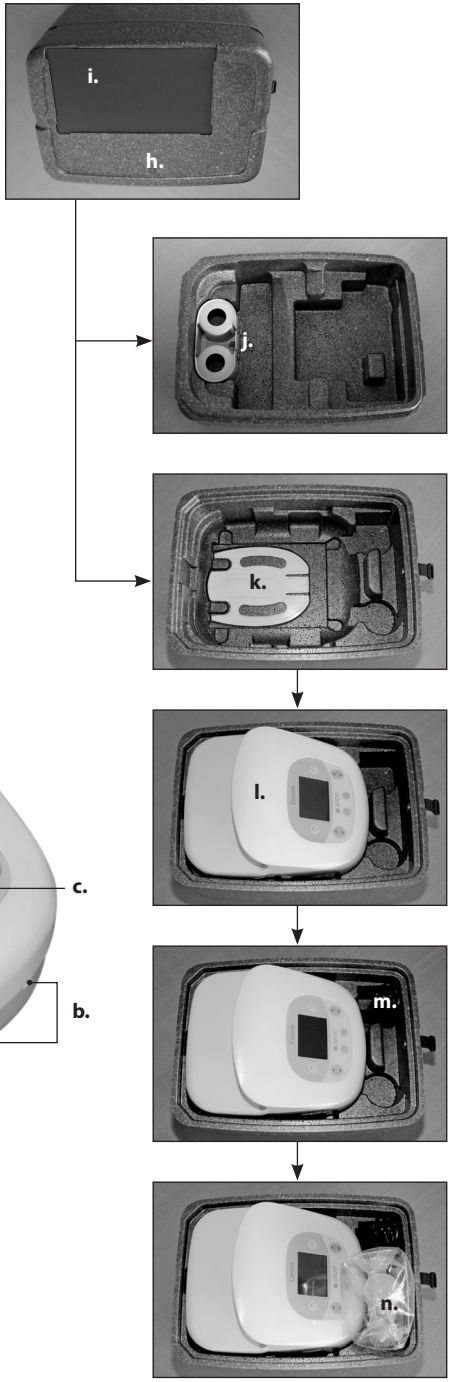
b. Connection opening for PumpSet
c. Control panel with LCD
d. Connection for power cord
e. Bottle holder
f. EasyFreeze holder
g. Power cord

h. Carum Container
i . Address field
j. Bottle holder
k. EasyFreeze holder
l. Carum
m. Power cord
n. PumpSet





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Congratulations on your purchase, and thank you for choosing the gentle Carum breastpump from ARDO.

In these instructions you will find important and useful details which will make your Carum experience even more rewarding.

When using electrical devices it is very important to observe the following safety regulations. Please take the time carefully to read the user manual before using the Carum for the first time. Please start with Section 4 - (Start-up / Operation) – before you plug your Carum into the power supply, or connect to the car battery (optional cable) or start battery operation mode (optional).

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1. IMPORTANT SAFETY DETAILS

Carum is an electrically-operated, safe and reliable breastpump for personal use. Carum is constructed and assembled in accordance with CE guidelines, and in compliance with Security Standards EN 60601-1, EN 60601-1-2, EN ISO 10079-1, EN 60601-1-4 and EN 60601-1-6 and EN 60601-1-11 . For your safety, to avoid damage to the unit and to avoid risk of electric shock, injury or fire, please observe the following safety regulations.

Safety Regulations ⚠

- After use, disconnect Carum from the outlet.
- In the event of an accidental splash, or the unit falling into water - IMMEDIATELY disconnect it from the outlet. Do not touch the unit until it has been disconnected.
- Disconnection from the outlet is only guaranteed if the outlet plug is pulled out of the socket. ☝
- The unit is designed for indoor use only. Do not use outdoors.
- Use only the original power cord or car battery cable from ARDO.
- Do not open the unit (results in voiding of the warranty).
- Carum is not water-proof. Therefore the unit must never be immersed in water or other fluids, nor used or stored in places where it might fall into the water. Do not use while in the bath or while taking a shower.
- Keep the power cord and all accessories away from sources of heat.
- Do not use Carum in an area where oxygen gas is in use or sprays are being applied.
- Only use a genuine ARDO PumpSet and genuine ARDO parts. See Section 4. (Start-up / Operation) and Section 8 (Maintenance / Care / Cleaning).
- Carum should only be used for the purposes detailed in Section. 2 (Application).

Battery option and car battery adapter

- The unit is designed for indoor use only. Do not use outdoors.
- If the operating time of the battery declines from fully charged to less than one hour (of charge), the battery should be changed as soon as possible, to ensure safe operation of the Carum when on battery power. See Section 8: Maintenance / Care / Cleaning.
- Do not use the Carum out in the open when operating on the car cigarette-cable.
- Caution: Ensure that the car battery delivers 12 volts.
- The unit must not be altered or changed without the express permission of the manufacturer. ⚠
- Any alteration or change to the Carum is not permitted. ⚠
- If the Carum must be altered or changed to ensure safe continued use, the appropriate studies and testing must be carried out. ⚠
- Please keep this User Manual handy for reference at all times. ☝

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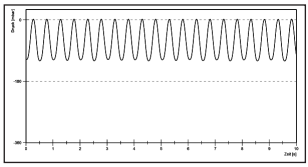
2. PRODUCT DESCRIPTION

The Carum Pump System consists of the breast pump and a PumpSet (single or double pumpset).
The Carum breast pump is a quiet, user-friendly double piston pump for hospital use and for rental use.
The unit is equipped with a robust plastic housing (Quality: VO) and a simplified, logically organised keyboard with a LCD display readout.
The energy-saving electrical equipment is designed for outlet operation, for use with the car charger, or for (optional) battery use.
The sophisticated controls allow each mother to enjoy a comfortable and efficient pumping experience (plus a tested suckling curve) thanks to the flexible system for adjusting vacuum and cycles.

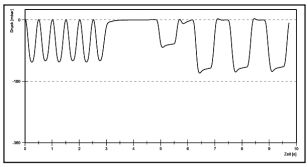
2.1. Suckling Curve

The suckling curve is characteristically stable over the entire vacuum and cycle area and corresponds closely to your baby's suckling behaviour. Therefore the breast tissue is not additionally stressed by pumping.

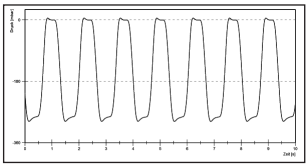
Stimulation mode



Exchange Stimulation-Expression



Expression mode



3. INDICATIONS FOR USE

3.1. Indications

The ARDO Carum powered breast pump is intended to be used by lactating women to express and collect milk from their breast.
It can be used as a single pump and as a double pump. The unit is intended for indoor use only and is intended for multiple users.

3.2. Contra- indications

None known: when the unit is used for the correct purpose.

4. START-UP / OPERATION

4.1. Icons

Read the manual

Important information

"ON / OFF" switch

Suckle strength / Adjust the vacuum (V)

Change the cycles level / number (C)

Switch stimulation mode / express mode

Backlight change (light / dark)

Time measurement (on / stop / off)

Unit with the applied part BF

Cleaning

Single pumpset / Double pumpset (applied part)

Warning: General risk points – check the Instruction Manual

Assembling

Compliance with general guidelines: MDD 93 / 42 EWG and MDD 2009

Manufacturer

The unit is compliant with the stipulations of the WEEE 2002 / 96 / EG guidelines

Power cord

Device of protection category II

IP21 IP 21 drip proof

Li-Ion Contains a lithium ion battery

Express mode

Stimulation mode

Device is recyclable

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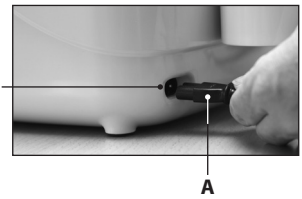
4.2. Installation ⚠

4.2.1. Electrical connection

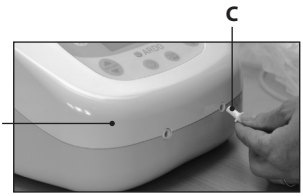
- Outlet operation: Insert power cord (A) into the Carum (B) input socket (Fig.1) and connect the local power plug to the wall outlet.
- Battery operation: Before using the battery for the first time, connect the unit to an outlet for 6 hours.



4.2.2. Connecting the PumpSet

Use of the PumpSet is detailed in the separate user manual: "ARDO PumpSet". The PumpSet is an applied part of the pump. ⚠

- To use the single PumpSet:
  Attach the tube connector (C) to the unit (D). (Fig. 2).



- To use the double PumpSet:
  Attach the tube connector to the unit (Fig 3).

- The second opening of the tube connector (E) remains closed – by single and double pumping.

4.2.3. Installing the bottle holder

The bottle holder is used for short-term storage of the PumpSets. The bottle holder is designed to protect against accidental spilling of milk. The bottle holder can be used free-standing or be plugged into the back of the Carum

4.2.4. Installing the EasyFreeze holder

The easy freeze holder is used for short-term hang up of the PumpSet with bag. The EasyFreeze holder is designed to protect against accidental spilling of milk. The EasyFreeze holder can be plugged onto the back of the Carum instead of the bottle holder.

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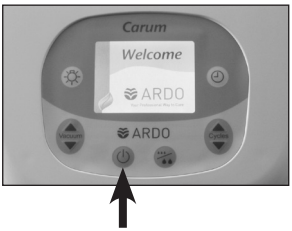
4.3. Operation ⚠

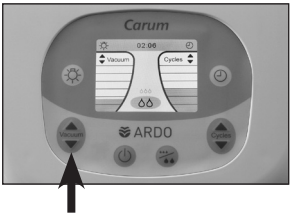
Vacuum and cycles can be adjusted independently of each other. Select the adjustment which is the most comfortable for you.

4.3.1. Switch on / switch off



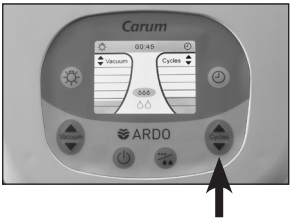
Switch on the unit by pressing the "ON / OFF" button once.
A 'welcome' page will be displayed.
When it is switched on, the breast pump is in stimulation mode (orange display). Medium vacuum and cycle level. To turn the unit off, press the "ON / OFF" button once again.
The "ON / OFF" function is the same for battery operation, electrical outlet power supply or 12vDC power supply (car battery operation).
Display mode:
The operation mode is shown on the illuminated LCD display. The display turns off when the unit is switched off.

4.3.2. Regulation of the vacuum and display



The vacuum (suction strength) can be adjusted, **one level at a time**, by **repeatedly pressing**, or by **holding down** the vacuum button (to the left side of the key pad). The vacuum strength can be individually regulated in both stimulation mode and expression mode.
Pressing the 'up' arrow increases the vacuum, pressing the 'down' arrow reduces the vacuum. The vacuum strength is displayed on the bar chart to the left.

4.3.3. Cycle regulation and display



The cycles (frequency) can be adjusted, **one level at a time**, by **repeatedly pressing**, or by **holding down** the cycle button (to the right side of the key pad). The cycle can be individually regulated in both stimulation mode and expression mode.
Pressing the 'up' arrow increases the cycles level, pressing the 'down' arrow reduces the cycles level. The cycles level is displayed on the bar chart to the right.

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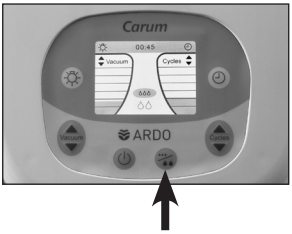
4.3.4. Switch stimulation mode / expression mode

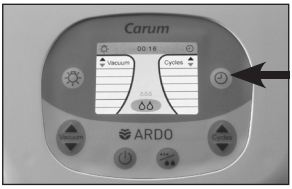


To change the stimulation mode display screen (orange display) to the express mode display screen (green display), press the 'Mode' button just to the right of the "ON / OFF" button.
The change can be made at any time by pressing the 'Mode' button.
If the Carum is in stimulation mode and the 'Mode' button is not pressed, the unit will automatically change to express mode after 2 minutes. Press the 'Mode' key to return to stimulation mode.
When the mode changes, the background colour of the LCD screen changes accordingly. In addition, the symbol relevant to stimulation or expression mode will be highlighted on the LCD display.
Background colour in stimulation mode is orange.
Background colour in expression mode is green.
In each separate mode of operation, vacuum strength and cycles level can be individually adjusted.
When changing from stimulation mode to expression mode, the vacuum strength will automatically be set to 30mbar, and the cycles level to 45 cycles, from the previously set values.
When changing from express mode to stimulation mode, the vacuum strength will be set to 60mbar, and the cycles level to 90 cycles. These values also apply when the unit is switched on.

4.3.5. Using express mode, skipping stimulation mode ("Sensitive Programme")

If the 'mode' button is pressed within 2 seconds of switching on the Carum, stimulation mode is skipped. Express mode starts with an especially mild, gentle and low level vacuum of 30mbar and a cycles level of 30 cycles.

4.3.6. Timing / Time Button



Timing starts automatically when the Carum is switched on. To stop timing, press the 'time' button. Timing will remain de-activated until re-started by pressing the 'time' button again, or until the unit is turned off. The timer will be reset to 00:00 when the 'time' button is pressed for a second time.
Press the 'time' button again to restart the timer. The timer can be switched on and off in either stimulation or express mode.

4.3.7. Backlight

Using the Carum in a darkened room can be made more comfortable by dimming the intensity of the LCD. To reduce the intensity of the backlighting, press the 'light' button (to the left of the LDC) once.
The dim function can be turned on and off as required.

5. USEFUL TIPS

5.1. Adjusting the vacuum (intensity of suction)
Expressing milk should never be painful.

- Set the vacuum intensity at the highest level which is comfortable to you. If you are experiencing any discomfort of pain while pumping, you should decrease the vacuum intensity.
- Take care that the nipple is centred in the breast-shell.
- Check whether the size of the breast-shell fits your nipple. (See the User Manual: "ARDO PumpSet").
- In the event that the milk is not released, try massaging the breast – this can be really effective.

Regulate the vacuum by touching the arrow keys.

- Intensify the vacuum, until you feel a very slight discomfort, and then reduce the intensity of the vacuum until pumping is comfortable.
- In the event of sore nipples or painful breasts, skip the stimulation mode. The Carum will then start in express mode with an especially mild, gentle and low level vacuum.
- It is recommended that, in pump- or stimulation mode, you adjust the suction strength each time to suit your personal comfort level. This is because the vacuum level generated is sensitive to prevailing atmospheric pressure.

5.2. Regulate the cycle

- When babies start to breast feed, they suckle with rapid sucking motions and low suction – this causes the milk to release by stimulating the milk ejection reflex.
  For this reason, the Carum will automatically start in stimulation mode, i.e. with a higher cycles level and a lower vacuum strength, mimicking the baby's natural behaviour.
- Select stimulation mode, choose the level of vacuum which feels most comfortable.
- When the milk begins to flow, the baby's sucking pattern changes. The baby sucks more slowly, but more strongly. Change to express mode, and strengthen the vacuum and raise the cycles level by pressing the arrow until a comfortable pumping experience is achieved.
- If the milk flow falters, return to stimulation mode to prompt renewed milk flow.

5.3. Encouraging the Let down reflex

The milk ejection reflex may occur later when pumping than when breast feeding. The following measures may be helpful.

- Have a warm drink.
- Relax and think about your baby.
- Look at a picture of your baby.
- Apply a warmed compress to the breast before expressing (e.g. ARDO Temperature Pack).
- Warm the cone or funnel of the breast shell before applying.

5.4. Pump efficiently

- Massaging the breast while using the breastpump can boost milk production, and promote better milk flow.

5.5. Increase the quantity of milk

- Use a double pump-set.
- For the first 10 minutes, or until no more milk is flowing, use a double pump i.e. express from both breasts at once. Afterwards, switch to a single pump. Express from each breast for five minutes while massaging gently.

6. ACCESSORIES

Power cord Euro	Art. No. 63.00.130
Power cord UK	Art. No. 63.00.131
Power cord UL	Art. No. 63.00.132
Trolley - optional	Art. No. 63.00.129
Car battery adapter 12VDC - optional	Art. No. 63.00.133
Bottle holder	Art. No. 63.00.127
EasyFreeze holder	Art. No. 63.00.128
Various pumpsets	www.ardomedical.com

7. ERROR ANALYSIS / ERROR DISPLAY / SERVICE INDICATOR

Identifiable errors or service / maintenance schedules are represented on the LCD by a warning triangle.

	Switch the unit off, and then on again. If the error message comes up again, return the unit to the supplier. The unit must be repaired by trained service personnel, or by the manufacturer.
	Error: the unit does not work on battery power i.e. the pump does not operate. Solution: Connect the unit to an outlet to recharge the battery. The battery charging time is ca. 4 hrs. Advice: The unit may be used while the battery is being charged, but this will extend the charging time.

7.1. Further possible errors when using the unit

- Weak or absent vacuum
  Disconnect the PumpSet from the unit. Partly close the connector opening with a finger to test the suction. If suction is de-tectable, then the pump is working. Test the PumpSet in accordance with the separate instructions, (only use the original ARDO PumpSet)
- The pump is not working / no data on the LCD display
  Check the power supply; if the unit still does not work, it is defective

Should any of these errors occur, and be confirmed, return the unit to the supplier immediately. The unit must be repaired by trained service personnel or by the manufacturer.

8. MAINTENANCE / CARE / CLEANING

The silicone pot integrated into the PumpSet constitutes a total barrier, and ensures that neither breast milk nor pathogenic agents can get into the pump unit. The unit is maintenance-free; care of the unit, and its accessories, is limited to inspection and cleaning.

The Carum breast pump can be repaired, but only by trained service personnel or by the manufacturer. For this reason, only the bottle holder, the EasyFreeze holder, the connector cable, and the car charging cable, are available for order as spare parts. See Section: Accessories / Spare Parts.

8.1. Visual inspection before switch-on

- Is the pump housing intact?
- Is the power unit undamaged?
- Is the accessory clean, complete and intact?
- Is the accessory correctly attached?

Ignoring these checks, or the cleaning instructions, may lead to risk of infection, electric-shock or damage to the unit.

8.2. Cleaning / disinfection

- Carum breast milk pump:
  Important: unplug the unit from the power supply before cleaning.
- The Carum is not waterproof. It conforms to enclosure IP (Ingress Protection) rating IP20.
  Cleaning at home: As needed, wipe with a damp cloth, commercial detergent may be used.
  Cleaning in the hospital: Disinfect by wiping with a non-phenol based disinfectant.
  Do not put the unit into the dish-washer or into a washing-up bowl. It is not possible to clean the pump or the power unit. Attempting to do so may cause the unit to malfunction or to become contaminated – requiring suitable disposal. (See section 11: Transport / Storage / Disposal).
- Accessory PumpSet: Please read the separate User Manual, Section: Cleaning.

8.2.1. Checklist: Maintenance inspections for rentals

• Visual inspection of the pump for cleanliness	After every renting
• Visual inspection of the pump for completeness	After every renting
• Visual inspection of the pump for damage	After every renting
• Simple operational checks of the pump (Pump runs properly, battery charged	After every renting
• Check of the vacuum strength – to be carried out by trained service personnel	Minimum every 2 years

8.2.2. Checklist: Maintenance inspection for hospitals

• Visual inspection of the pump for cleanliness	Before every use
• Visual inspection of the pump for damage	After every use
• Check of the vacuum strength – to be carried out by trained service personnel	Minimum every 2 years

9. GUARANTEE

The Carum is guaranteed for 3 years from the date of purchase. The purchase invoice serves as proof of guarantee.

General terms and conditions

This unit is covered by the Ardo medical AG warranty in respect of materials and manufacturing defects.
The guarantee starts from the date of purchase. Defective materials will be replaced free-of-charge, during the life of the Guarantee, provided that the Guarantee has not been voided by unauthorised use or access to the unit.
To ensure guarantee cover, and the flawless functioning of the unit, the instructions in the User Manual must be followed and only Ardo medical AG accessories used. The guarantee is void if the unit has been opened.

10. TECHNICAL INFORMATION

10.1. Version

Carum with Euro power cord	Art. No. 63.00.71	Carum battery with Euro power cord	Art. No. 63.00.75
Carum with UK power cord	Art. No. 63.00.72	Carum battery with UK power cord	Art. No. 63.00.76
Carum with UL power cord	Art. No. 63.00.73	Carum battery with UL power cord	Art. No. 63.00.77

10.2. Technical data

Pump dimensions	L x B x H = 302 x 240 x 180 mm	Power cable length	Length 3 m
Pump weight	3 kg	Weight with battery	3.7 kg
Input voltage	100 – 230 VAC +/-10%	Frequency	50 – 60Hz
DC Input	12 VDC	Lifetime (excluding parts subject to wear and tear)	10 years
Operating temperatures	+5 – +40 °C	Relative humidity	10 – 93%
Protection level	BF	Air pressure	700 – 1060 hPa
Protection Category Double Insulated	Category II	Classification in accordance with MDD93/42	Category 2a

Cycle and vacuum levels

Vacuum range in stimulation mode	30 – 150 mbar 22 – 98 mmHg 3 – 13 kPa	Cycle range in stimulation mode	72 – 120/min.
Vacuum range in expression mode	30 – 330 mbar 22 – 250 mmHg 3 – 33 kPa	Cycle range in expression mode	30 – 60/min.
Permitted tolerance of the vacuum strength	+/- 5%	Permitted tolerance of the cycles	+/- 3 cycles

The vacuum level generated is sensitive to prevailing atmospheric pressure. The higher the prevailing atmospheric pressure, the more intense the generated vacuum – and vice versa. The vacuum values (including tolerances) specified in the user manual are based on an atmospheric pressure of 880hPa.

10.3. Compliance

In accordance with guidelines: MDD 93/42 CEE, 2006/42/CE, EN 60601-1, EN60601-1-2, EN ISO 10079-1, EN 60601-1-4, EN 60601-1-6, EN 60601-1-11	CE 0123

10.4. EMV Test records

See annex 12.1.

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11. TRANSPORT / STORAGE / DISPOSAL

For the transport and storage of your Carum, we recommend using the original packaging. We further recommend separate storage for the unit is protected from UV (e.g. sunlight / halogen lamps), heat and dust.

11.1. Transport and storage conditions

Carum und Carum with optional battery

Temperature	-20 °C to +70 °C -4 °F to 158 °F
Relative humidity	10 – 80%
Atmospheric pressure	700 – 1060 hPa

11.2. Disposal

The unit may be returned to the manufacturer, or be dismantled and recycled (as metal or plastic) in an environmentally-friendly manner, through a recycling firm specialising in electrical goods. There are no special or increased risk factors.

Manufacturer:
Ardo medical AG
Gewerbestrasse 19
6314 Unterägeri
Switzerland

Homepage: www.ardomedical.com
Email: info@ardo.ch

EMV Prüfaufzeichnungen / Test Report

TEST REPORT

IEC / EN 60601-1-2

Part 1-2: Electromagnetic Compatibility Requirements and Tests

Report reference No:	**E1541-05-11**
Tested by:	B. Belegu
Approved by management:	Dr. F. Stucki
Date of issue:	26 April 2011
Number of pages:	1 page

Testing laboratory:	**QUINEL AG**	
Address:	Grundstr. 2 CH-6343 Rotkreuz	
Testing location:	Rotkreuz Tel. 041-799 47 04	STS 037

S T S Schweizerischer Prüfstellendienst / Service Suisse d'essai / Servizio di prova in Svizzera / Swiss testing service

Applicant's Name:	**Ardo Medical AG,** Mr. Christian Waser
Address:	Gewerbestrasse 19, CH-6314 Unterägeri
Manufacturer:	**Ardo Medical AG**
Address:	Gewerbestrasse 19, CH-6314 Unterägeri
Test specification:	
Standards:	IEC 60601-1-2:2007, EN 60601-1-2:2007
Test procedure:	Type testing for Swiss and EU legal requirements
Procedure deviation:	None
Non-standard test method:	None
Test-specification:	The used test setup fulfils the specification described in the relevant standards
Test item description:	Breast Pump
Trademark:	Ardo
Model and/or type reference:	Carum
Ratings:	100V-240V AC, 50Hz-60Hz
Date of receipt of the test item(s):	06 April 2011
Summary of testing:	**Passed**

Applied standards:

Title	**Standard** (up dated)
RF disturbances	CISPR 22:2008, EN 55022:2010
RF conducted disturbances	IEC 61000-4-6:2008, EN 61000-4-6:2009
Radiated electromagnetic field	IEC61000-4-3:2006+A1:2007+A2:2010, EN 61000-4-3:2006+A1:2008+A2:2010
Power frequency magnetic field	IEC 61000-4-8:2009, EN 61000-4-8:2010
Electrical fast transient burst	IEC 61000-4-4:2004+A1:2010, EN 61000-4-4:2004+A1:2010
Electrostatic discharge	IEC 61000-4-2:2008, EN 61000-4-2:2009
Surge	IEC 61000-4-5:2005, EN 61000-4-5:2006
Voltage dips - interruptions	IEC 61000-4-11:2004, EN 61000-4-11:2004
Harmonic current emissions	IEC 61000-3-2:2005+A1:2008+A2:2009, EN 61000-3-2:2006+A1:2009+A2:2009
Voltage fluctuations and flicker	IEC 61000-3-3:2008, EN 61000-3-3:2008

Acceptance criteria/operating conditions:

During and after the test the apparatus should show no damage or loss of information and should function according to specifications.

This Test Report is, together with the Test Report E1541-05a-11 and E1541-05b-11, valid for the following types: Carum 1, Carum 2

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